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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,756	12/21/2001	Terry L. Thomas	8383zyxwvut	6460

7590 07/14/2004
Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER

MCELVAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,756

Applicant(s)

THOMAS, TERRY L.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-55 is/are pending in the application.
- 4a) Of the above claim(s) 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47, 48 and 51-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Priority

1. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 08/934,254, filed September 19, 1997, which is now U.S. Patent 6,355,861." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 47, 48 and 51-55 in the reply filed on May 20, 2004 is acknowledged. The traversal is on the ground(s) that the claimed sequences are related structurally and functionally and are merely different aspects of a single invention and to prosecute each separately would be unduly expensive. This is not found persuasive because the DNA encoding delta-6 desaturase that is derived from species of different kingdoms would constitute structurally distinct molecules in the absence of evidence to the contrary. Claims 47 and 51-55 are considered linking claims, so that if the broad independent claim (claim 47) is deemed allowable, the groups would be rejoined.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claims 54 and 55 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can refer to other claims in the alternative only. See MPEP § 608.01(n). Examination of the claims does not relieve applicant of the requirement to correct the dependency.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 47, 48 and 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 is indefinite in the recitation of “delata”. Amendment of the claim to read “delta” would overcome the rejection.

Claim 48 is indefinite in the recitation of “wherein said isolated nucleic acid is a plant delta-6 desaturase”, because this reads that the DNA is actually a protein. Amendment of the claim to read that the nucleic acid encodes the delta-6 desaturase would overcome the rejection.

Claim 51 is indefinite in the recitation of “an isolated nucleic acid”, which should read “the isolated nucleic acid”.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47, 48 and 51-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to nucleic acid sequences that encode a delta-6 desaturase that may be from any species of any kingdom, and particularly from any plant species. However, applicant has not described any structural feature of the claimed nucleic acids that would define the genus. It remains unclear what nucleic acid sequence or combination of nucleic acid sequences are required to encode a protein having delta-6 desaturase activity, and the specification fails to provide such a description.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

7. Claims 47, 48 and 51-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acid sequences that encode a delta-6 desaturase from the plant species: evening primrose and borage, and from *Synechocystis* and cyanobacteria, does not reasonably provide enablement for any delta-6 desaturase from any species. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to nucleic acid sequences that encode a delta-6 desaturase that may be from any species of any kingdom, and particularly from any plant species. However, applicants have only disclosed nucleic acids encoding delta-6 desaturases from the two plant species: evening primrose and borage, and from *Synechocystis* and *anabaena*. The specification does not teach what sequences these nucleic acids have in common that identify them as delta-6 desaturases or how one would identify other nucleic acids that encode delta-6 desaturases. WO 99/27111 teaches that the delta-6 desaturase coding sequence from *C. elegans* has been cloned and that it “has a surprisingly low level of sequence identity with the known borage delta-6 desaturase” (see the abstract), having a sequence identity of less than 32% (page 4, lines 1-6). WO 99/27111 also teaches that desaturation at the delta-6 position “is an unusual modification in higher plants, occurring only in a small number of species such as borage, evening primrose and redcurrant” (page 2, lines 4-6). However, the specification does not teach other nucleic acids encoding delta-6 fatty acid desaturase from any other species, and the specification provides no guidance with regard to what other species comprise such a gene and what methods would be used to isolate said gene.

Furthermore, sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and “overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions” (the last sentence of the first paragraph of page 248). Doerks also teaches

homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that “there are numerous cases in which proteins of very different functions are homologous” (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different molecular and cellular functions” (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode fatty acid delta-6 desaturase activity, one cannot conclude that these other sequences also encode enzymes having fatty acid delta-6 desaturase activity. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that “on many occasions desired goals have been impossible to achieve” (see the

last paragraph on page 228N). Therefore, both the identification of other genes encoding fatty acid delta-6 desaturase activity, and the modification of plant lipid composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

Thus, given the unpredictability of identifying other sequences that exhibit fatty acid delta-6 desaturase activity and modifying the lipid composition of a plant with said sequences; the lack of guidance in the specification for identifying and characterizing other sequences that exhibit fatty acid delta-6 desaturase activity; the lack of working examples of fatty acid delta-6 desaturase activity coding sequences from other species, and the lack of working examples of similar sequences that encode proteins having the same activity; and the breadth of the claims which encompass nucleic acids encoding delta-6 desaturases from any and all species from any or all kingdoms, and use of said genes to modify a fatty acid in a cell or plant; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

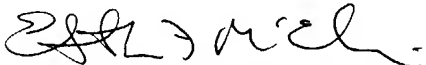
The claims are deemed free of the prior art given that a delta-6 fatty acid desaturase coding sequence was not taught or suggested by the prior art of record.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM